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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/420,692    10/19/99    BESTERMAN    J    106.101.197

NANCY CHIU PH D  
HALE AND DORR LLP  
60 STATE STREET  
BOSTON MA 02109

HM12/0920

EXAMINER

EPFS, J

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 09/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	<b>Applicant(s)</b>	<b>Applicant(s)</b>	
	09/420,692	BESTERMAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Janet L Epps	1635	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 October 1999.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-50 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-6, 11-41, and 46-50, drawn to a method and compositions for inhibiting the expression of a gene in a cell comprising contacting the cell with an effective amount of an antisense oligonucleotide which inhibits the expression of gene, and an effective synergistic amount of a protein effector of a product of the gene, wherein said gene encodes a DNA methyltransferase, classifiable in for example 435/6, 435/375, 514/44, 536/24.5.
  - II. Claims 1-4, 7-8, 11-39, 42-43, and 46-50, drawn to a method and compositions for inhibiting the expression of a gene in a cell comprising contacting the cell with an effective amount of an antisense oligonucleotide which inhibits the expression of gene, and an effective synergistic amount of a protein effector of a product of the gene, wherein said gene encodes a Histone deacetylase, classifiable in for example 435/6, 435/375, 514/44, 536/24.5.
  - III. Claims 1-4, 9-10, 11-39, and 44-50 drawn to a method and compositions for inhibiting the expression of a gene in a cell comprising contacting the cell with an effective amount of an antisense oligonucleotide which inhibits the expression of gene, and an effective synergistic amount of a protein effector of a product of the gene, wherein said gene encodes a

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Thymidylate Synthase, classifiable in for example 435/6, 435/375, 514/44, 536/24.5.

2. The inventions are distinct, each from the other because of the following reasons:
3. The inventions of groups I-III read on methods requiring the use of compositions comprising an antisense oligonucleotide which inhibits the expression of a target gene and a protein effector of a product of said target gene, wherein said target gene is selected from a DNA methyltransferase, a Histone deacetylase, and a Thymidylate Synthase. The genes encoding a DNA methyltransferase, a Histone deacetylase, and a Thymidylate Synthase are structurally and functionally distinct genes, which are transcribed into chemically different RNA molecules having unique secondary and tertiary folding patterns and furthermore having different accessible sites available for hybridization with complementary nucleic acid molecules. Therefore, antisense oligonucleotides designed to target the RNA molecules encoded by structurally distinct genes would comprise patentably distinct sets of antisense oligonucleotides and compositions comprising said antisense oligonucleotides. Moreover, methods requiring the use of distinct sets of antisense oligonucleotide compositions would also represent patentably distinct subject matter.
4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps whose telephone number is 703-308-8883. The examiner can normally be reached on Mondays through Friday, 9:00AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Janet L Epps  
Examiner  
Art Unit 1635

JLE  
September 19, 2001